UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257 PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs., Inc., et al.*, 02-CV-12084-PBS *State of Nevada v. American Home Products Corp., et al.*, 02-CV-12086-PBS	

MOTION OF THE COMMONWEALTH OF MASSACHUSETTS TO FILE A MEMORANDUM AS *AMICUS CURIAE* IN OPPOSITION TO THE DEFENDANTS' MOTIONS TO DISMISS ON THE GROUNDS OF PREEMPTION

1. The Commonwealth of Massachusetts moves for leave to file the attached Memorandum as Amicus Curiae in Opposition to the Defendants' Motions to Dismiss on the Grounds of Preemption. As grounds for this motion, the Commonwealth states that the Massachusetts Office of the Attorney General and its Medicaid Fraud Control Unit, in coordination with the Department of Justice and other states, is engaged in multiple ongoing investigations of drug manufacturers' violations of the Medicaid rebate program. In addition, the Commonwealth is the plaintiff in *Commonwealth of Massachusetts v. Mylan Laboratories, Inc., et al.*, C.A. No. 03-11865-PBS, a drug pricing action pending before this Court, in which it asserts Medicaid rebate claims against thirteen manufacturers of generic pharmaceutical products.

2. A finding of preemption in this action would seriously hamper the Commonwealth's Congressionally mandated enforcement efforts and prejudice its interests in the related pending litigation.

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS
By its attorney,

THOMAS F. REILLY
Attorney General

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January 9, 2004

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[PROPOSED] MEMORANDUM OF THE COMMONWEALTH OF MASSACHUSETTS AS *AMICUS CURIAE* IN OPPOSITION TO THE DEFENDANTS' MOTIONS TO DISMISS ON THE GROUNDS OF PREEMPTION

STATEMENT OF THE COMMONWEALTH'S INTEREST

The Commonwealth opposes the motions to dismiss on the basis of preemption because a ruling by this Court that state enforcement of drug manufacturers' rebate obligations is preempted could seriously hamper ongoing joint federal/state law enforcement efforts in connection with the Medicaid rebate program. Moreover, such a ruling would be inconsistent with Congressional intent as reflected in the rebate provisions of the Medicaid statute.

As part of the Medicaid program, Congress requires the states to establish oversight programs and Medicaid Fraud Control Units to identify and root out fraud and abuse in every aspect of the Medicaid program. *See* 42 U.S.C.§§ 1396a(a)(30), (37), (61); §1396b(q). The Commonwealth, through the Office of the Attorney General and its Medicaid Fraud Control Unit, in coordination with the Department of Justice and other states, is currently involved in

multiple investigations of drug manufacturers' violations of their Medicaid rebate agreements and their obligations under the rebate provisions of the Medicaid statute. For example, the Commonwealth has recently participated in two nationwide settlements of states' rebate claims against drug manufacturers, one with SmithKline Beecham Corporation in which the states' portion of the settlement was $38,269,148 (of which the Commonwealth received $1,797,016.21), and one with Bayer Corporation, in which the states' portion of the settlement was $108,956,961 (of which the Commonwealth received $3,727,074.52).

Another ongoing enforcement action by the Commonwealth has resulted in the filing of an action pending before this Court, *Commonwealth of Massachusetts v. Mylan Laboratories, Inc., et al.*, C.A. No. 03-11865-PBS. In the *Mylan* case, the Commonwealth asserts a variety of drug pricing claims against thirteen generic pharmaceutical manufacturers. These include claims alleging that the defendants, by providing false and inflated pricing information with the knowledge and expectation that the information would be used in the determination of reimbursement rates for their products, breached their obligations under their Medicaid rebate agreements and the rebate provisions of the federal Medicaid statute, in effect denying the Commonwealth the benefit of the rebates that they had agreed to.

Working groups representing the state Medicaid Fraud Control Units participate regularly in joint Medicaid investigations with the Department of Justice and investigate claims under the rebate provisions of the Medicaid statute, 42 U.S.C. § 1396r-8. These joint prosecutions include state claims for violations of the drug manufacturers' Medicaid rebate agreements, and the state share of Medicaid rebate damages may not be negotiated or settled without the approval of the states.

Such enforcement actions are actively supported by the United States Secretary of Health and Human Services (the "Secretary"). For example, on January 6, 2004, the Secretary promulgated an interim final rule extending the manufacturers' recordkeeping obligations under the rebate program as set out in 42 CFR Part 447, § 447.534(h) from three to ten years. Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program, 69 Fed. Reg 508 – 14 (2004). A true copy of the regulation is attached hereto as Attachment A. In the Analysis of and Responses to Public Comments included with the announcement of the rule, the Secretary explained that the purpose of the change is to accommodate federal *and state* enforcement activities with regard to rebate program fraud:

> *Comment:* Several commenters noted strong opposition to the 3-year recordkeeping requirement, expressing concern with any provision that could permit the destruction of potential evidence of fraud and thereby interfere with efforts to eliminate fraud related to the Medicaid program. . . .
>
> * * *
>
> *Response:* We concur . . . . After further consideration, we believe that, *due to potential fraud and abuse violations and litigation*, a 10-year recordkeeping requirement will be more appropriate and sufficient to ensure a Federal standard with regard to the Medicaid drug rebate program *that will not hinder the activities of Federal and State law enforcement officials*. (Emphasis added.)

69 Fed. Reg. at 510.

Federal/state enforcement of the rebate program is fully consistent with the statutory scheme adopted by Congress in the rebate program. Congress established the states as parties to, or at least third-party beneficiaries of, the rebate agreements, with the full array of contractual rights to enforce them directly. By doing so and incorporating contractual remedies, Congress placed enforcement power in the hands of the states, the parties most directly affected by the manufacturers' failure to pay the required rebates.

Enforcement of the rebate program is just one facet of the overall joint federal/state oversight of the Medicaid program, in which the principal of "cooperative federalism" is paramount. *Pharmaceutical Research and Mfrs. of America v. Concannon*, 249 F.3d 66, 75 (1st Cir. 2001). A ruling that the states' claims under drug manufacturers' Medicaid rebate agreements are preempted would seriously disrupt this carefully crafted joint federal-state mechanism for enforcement of the Medicaid program generally and rebate agreements in particular.

ARGUMENT

I. CONGRESS DID NOT INTEND TO PREEMPT STATE ENFORCEMENT IN THIS SINGLE AREA OF THE MEDICAID PROGRAM

A. *A Finding of Preemption is Warranted Only Upon a Clear Showing of Congressional Intent*

In the context of the Medicaid program, a finding of preemption is warranted only upon a clear showing of congressional intent to preempt. *Pharmaceutical Research and Mfrs. of America v. Concannon*, 249 F.3d 66, 75 (1st Cir. 2001). The rebate provisions of the Medicaid statute do not expressly preempt the states' enforcement of the rebate agreements. A finding of preemption, therefore, is possible only if the defendants have shown that state enforcement actions are an obstacle to the achievement of Congress's discernable objectives as set out in the rebate program. *Id.* at 74 – 75; *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp.2d 172, 189 (D. Mass. 2003). The structure of the program itself shows that state enforcement of the rebate agreements is essential to the accomplishment of the full purposes and objectives of Congress in enacting the rebate program.

B. *By Making the States Parties to or Intended Third-Party Beneficiaries of the Rebate Agreements, Congress Expressed an Intent that State Enforcement Actions Not be Preempted*

Medicaid rebate agreements are not federal procurement contracts. Rather, they are agreements to which, as a matter of federal common law, the states are parties or at least third-party beneficiaries. This is because they are entered into by the states directly with manufacturers or by the Secretary "on behalf of" the states; the states incur obligations as well as receive benefits under them; and they are intended for the express benefit of the states.

The Medicaid statute provides that "[i]n order for payment to be available under section 1396b(a) of [the Medicaid Statute] for covered outpatient drugs of a manufacturer," the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of the statute, either with the Secretary of HHS "*on behalf of States"* or, if authorized by the Secretary, with a state directly. 42 U.S.C. § 1396r-8(a)(1). (Emphasis added.) A copy of the form of the rebate agreements is attached hereto as Attachment B. The first sentence of the form recites that "[t]he Secretary, *on behalf of* the Department of Health and Human Services *and all States and the District of Columbia* (except to the extent that they have in force an Individual State Agreement) . . . [enters into the agreement] . . . ." (Emphasis added.) Attachment B, p. 1. It is a basic tenet of agency and contract law that, when an agent makes a contract *on behalf of* a disclosed principal, the principal is a party to the contract and may enforce it directly.[1] *See* Restatement (Third) of Agency § 6.01 (T.D. No. 4, 2003). Under federal common law and general principles of contract law, a party to a contract ordinarily has standing to seek enforcement of a contractual promise made to it by another party. *Almond v. Capital Properties, Inc.*, 212 F.3d 20, 24 (1st Cir. 2000).

[1] Federal common law incorporates general principles of contract and agency law. *See InterGen N.V. v. Grina*, 344 F.3d 134, 144 (1st Cir., 2003).

Second, Congress has mandated that the states incur obligations as well as receive benefits under the agreements. 42 U.S.C. § 1396r-8(b) specifies the required terms of the rebate agreements. Under 42 U.S.C. § 1396r-8(b)(2)(A), entitled "State responsibility," the rebate agreements must obligate each state, at the end of each quarter, to report to each manufacturer and the Secretary the total number of units of the manufacturer's drugs for which payment was made to providers under the state's Medicaid plan during the quarter. Under 42 U.S.C. § 1396r-8(b)(2)(B), a rebate agreement must obligate the states to permit the manufacturer to audit the information "provided (or required to be provided)" under subparagraph (A). The states are also explicitly required to keep pricing data confidential. 42 U.S.C. § 1396r-8(b)(3)(D). Accordingly, the rebate agreements impose these obligations directly on the states. Section V(b) of the form Rebate Agreement provides that, in the event of a dispute between the state and manufacturer as to amounts due, "[t]he balance due, if any . . . will be paid or credited by the Manufacturer or the State . . . ." Attachment B at p. 7. (Emphasis added.) Subpart (c) in the same section obligates the states "to use their best efforts" to resolve any disputes. *Id.* at p. 8. Section VII(a), which defines the confidentiality provisions, prohibits disclosure "by the Secretary or State Medicaid Agency . . . ." *Id.* The imposition of such obligations pursuant to the rebate agreements is not possible unless the states are parties to them.

Third, the fundamental purpose and intent of Congress in establishing the rebate program was to benefit the states, i.e. to ensure that the states' Medicaid plans have the benefit of the best prices for covered drugs available in the market. See H.R. Rep. No. 881, at 82 – 83 (1990), reprinted in 1990 U.S.C.C.A.N. 2017, 2108 – 09 ("The committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. . . "). In the *History of*

the Medicaid Drug Rebate Program published on the Centers for Medicare and Medicaid Services' website, the Secretary describes the rebate program's purpose as "affording state Medicaid programs the opportunity to reimburse pharmacies for drugs at discounted prices similar to those offered by pharmaceutical Manufacturers to other large purchasers." See www.cms.hhs.gov/medicaid/drugs/mrphistory.asp

Under federal common law, an intended third-party beneficiary who is not a party to a contract may nevertheless have enforceable claims under the contract if the contract was made for its direct benefit. *Taylor Woodrow Blitman Const. Corp. v. Southfield Gardens Co.*, 534 F. Supp. 340, 343 (D. Mass. 1982). As parties to, or at least intended third-party beneficiaries, the states may, as a matter of federal common law, enforce the rebate agreements directly.

C. *State Enforcement of the Rebate Agreements is Fully Consistent With the Statutory Scheme Adopted by Congress*

In the context of the contract-based rebate scheme adopted by Congress, the states' enforcement of the rebate agreements is not in conflict with the accomplishment of the full purposes and objectives of Congress in enacting the rebate legislation. Rather, it is essential to its full implementation.

While Congress could have simply mandated that the manufacturers pay the states the statutorily defined rebates in order to accomplish its purpose, it did not do so. Instead, Congress required the manufacturers to enter into rebate agreements, either nationally with the Secretary on behalf of the states, or with the states directly. Congress's purpose in adopting a contractual mechanism to administer and enforce the rebate program, rather than imposing statutory obligations on the manufacturers and states directly, was to incorporate the normal array of contractual duties and remedies into the rebate agreements. There is nothing in either the statute

or the rebate agreements themselves that indicates that normal contract remedies are not available.

The defendants claim that the penalty provisions in Section (b) (3) of the Rebate Statute and in Part IV of the rebate agreement are the exclusive means of enforcing the rebate agreements. However, these provisions do not apply to any breaches of the agreements other than the manufacturers' failure to provide pricing information as and when required. Rebate Agreement, Exhibit A, at Part IV, page 7. Congress could not have intended that the penalty provisions be the only enforcement mechanism because, in that event none of the other provisions of the agreements would have been enforceable. The remedies for any other violation (the failure to pay the appropriate rebates when due, for example) are left to the parties' normal contractual remedies. Moreover, the language of the Rebate Statute explicitly provides that the penalty provisions are not exclusive. 42 U.S.C. § 1396r-8(b)(3)(C)(ii). There is absolutely no abrogation of or limitation on the normal contractual remedies for any party.

CONCLUSION

The Commonwealth respectfully requests that the Court deny the defendants' request for a ruling that state enforcement of the Medicaid rebate agreements is preempted by the rebate provisions of Medicaid.

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS

THOMAS F. REILLY
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January 9, 2004

ATTACHMENT A

information may be received which may relate to a case under the investigative jurisdiction of another agency. The maintenance of this information may be necessary to provide leads for appropriate law enforcement purposes and to establish patterns of activity which may relate to the jurisdiction of other cooperating agencies.

(D) From subsection (e)(2) because collecting information to the fullest extent possible directly from the subject individual may or may not be practical in a criminal and/or civil investigation.

(E) From subsection (e)(3) because supplying an individual with a form containing a Privacy Act Statement would tend to inhibit cooperation by many individuals involved in a criminal and/or civil investigation. The effect would be somewhat adverse to established investigative methods and techniques.

(F) From subsections (e)(4)(G), (H), and (I) because this system of records is exempt from the access provisions of subsection (d).

(G) From subsection (e)(5) because the requirement that records be maintained with attention to accuracy, relevance, timeliness, and completeness would unfairly hamper the investigative process. It is the nature of law enforcement for investigations to uncover the commission of illegal acts at diverse stages. It is frequently impossible to determine initially what information is accurate, relevant, timely, and least of all complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light.

(H) From subsection (e)(8) because the notice requirements of this provision could present a serious impediment to law enforcement by revealing investigative techniques, procedures, and existence of confidential investigations.

(I) From subsection (f) because the agency's rules are inapplicable to those portions of the system that are exempt and would place the burden on the agency of either confirming or denying the existence of a record pertaining to a requesting individual might in itself provide an answer to that individual relating to an on-going investigation. The conduct of a successful investigation leading to the indictment of a criminal offender precludes the applicability of established agency rules relating to verification of record, disclosure of the record to that individual, and record amendment procedures for this record system.

(J) From subsection (g) because this system of records should be exempt to the extent that the civil remedies relate to provisions of 5 U.S.C. 552a from which this rule exempts the system.

(iv) *Authority:* (A) Investigative material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(B) Therefore, portions of this system of records may be exempt pursuant to 5 U.S.C. 552a(k)(2) from the following subsections of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f).

(v) *Reasons:* (A) From subsection (c)(3) because to grant access to the accounting for each disclosure as required by the Privacy Act, including the date, nature, and purpose of each disclosure and the identity of the recipient, could alert the subject to the existence of the investigation. This could seriously compromise case preparation by prematurely revealing its existence and nature; compromise or interfere with witnesses or make witnesses reluctant to cooperate; and lead to suppression, alteration, or destruction of evidence.

(B) From subsections (d) and (f) because providing access to investigative records and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(C) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(D) From subsections (e)(4)(G) and (H) because this system of records is compiled for investigative purposes and is exempt from the access provisions of subsections (d) and (f).

(E) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants.

(F) Consistent with the legislative purpose of the Privacy Act of 1974, the AF will grant access to nonexempt material in the records being maintained. Disclosure will be governed by AF's Privacy Regulation, but will be limited to the extent that the identity of confidential sources will not be compromised; subjects of an investigation of an actual or potential criminal or civil violation will not be alerted to the investigation; the physical safety of witnesses, informants and law enforcement personnel will not be endangered, the privacy of third parties will not be violated; and that the disclosure would not otherwise impede effective law enforcement. Whenever possible, information of the above nature will be deleted from the requested documents and the balance made available. The controlling principle behind this limited access is to allow disclosures except those indicated above. The decisions to release information from these systems will be made on a case-by-case basis.

* * * * *

Dated: December 24, 2003.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–24 Filed 1–5–04; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2175–IFC]

RIN 0938–AM20

Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: On August 29, 2003, we published a final rule with comment period in the **Federal Register** that finalized two specific provisions: it established new 3-year recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program and set a 3-year time limitation during which manufacturers must report changes to average manufacturer price and best price for purposes of reporting data to us. In addition, it announced the pressing need for codification of fundamental recordkeeping requirements. On September 26, 2003, we issued a correction notice to change the effective date of the August 29, 2003 rule from October 1, 2003 to January 1, 2004.

In this interim final rule with comment period, we are removing the 3-year recordkeeping requirements, replacing them with 10-year recordkeeping requirements on a temporary basis, and soliciting comments on the 10-year requirements.

Manufacturers must retain records beyond the 10-year period if the records are the subject of an audit or a government investigation of which the manufacturer is aware. These provisions contain a sunset date with respect to the record retention requirements to ensure that we reexamine whether the retention rule remain necessary and effective.

This interim final rule with comment period also responds to public comments on the August 29, 2003 final rule with comment period that pertain to the 3-year recordkeeping requirement at § 447.534(h).

EFFECTIVE DATE: This rule is effective January 1, 2004.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 8, 2004.

ADDRESSES: In commenting, please refer to file code CMS–2175–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

Mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2175–IFC, P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201,

or

Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Marge Watchorn, (410) 786–4361.

SUPPLEMENTARY INFORMATION: *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background

In this interim final rule with comment period, we are removing the 3-year recordkeeping requirements, replacing them with 10-year recordkeeping requirements on a temporary basis, and soliciting comments on the 10-year requirements. Manufacturers must retain records beyond the 10-year period if the records are the subject of an audit or a government investigation of which the manufacturer is aware. These requirements regarding record retention will be in effect until December 31, 2004 or when we publish final recordkeeping requirements in the **Federal Register**, whichever occurs first.

We are also publishing this interim final rule with comment period to address some of the comments received on the final rule with comment period we published on August 29, 2003 (68 FR 51912). Specifically, we are addressing comments pertaining to the 3-year recordkeeping requirements at § 447.534(h). The 3-year recordkeeping requirement for drug manufacturers participating in the Medicaid drug rebate program has caused a significant amount of concern from commenters with regard to the rule's potential effect on the False Claims Act (FCA) and other possible fraud and abuse violations.

II. Provisions of the Final Rule With Comment Period

On August 29, 2003, we published a final rule with comment period (68 FR 51912) in the **Federal Register** that finalized two specific provisions: It established new recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program and set a 3-year time limitation during which manufacturers must report changes to average manufacturer price and best price for purposes of reporting data to us. In addition, it announced the pressing need for codification of recordkeeping requirements. On September 26, 2003, we issued a correction notice (68 FR 51912) to delay the effective date of the August 29, 2003 rule from October 1, 2003 to January 1, 2004.

III. Analysis of and Responses to Public Comments

We received 12 public comments in response to the August 29, 2003 rule. We received comments from State government officials, representatives of the pharmaceutical industry including manufacturers, attorneys, consultants, provider representatives, and a non-profit organization. We received comments on a variety of topics pertaining to the final rule with comment period, as well as comments pertaining to the general Medicaid drug rebate program. For example, several commenters raised issues regarding disputes under the Medicaid drug rebate program, which were not addressed in the August 29, 2003 rule. We are not responding to comments that pertain to the 3-year time limitation for price recalculations at this time; we intend to respond to those comments in a subsequent document that we will publish in the **Federal Register**. In this document, we are summarizing and responding to those comments that pertain to the 3-year recordkeeping requirements at *§ 447.534(h).* These comments and our responses are summarized below:

Recordkeeping Requirements at § 447.534(h)

Comment: One commenter noted that there is significant crossover between data required under the Medicaid drug rebate program, section 340B of the Public Health Service Act, and section 603 of the Veterans Health Care Act (VHCA). The commenter indicated that this rule is inconsistent with the 5-year record retention requirement in the VHCA. The commenter also requested that we define the term, ''authorized government agency,'' as it appeared in section IV of the August 29, 2003 rule. As written, this term implies that if, for example, the Department of Veterans Affairs (DVA) determines that a manufacturer's underlying pricing data contain errors, then the manufacturer must retroactively revise average manufacturer price or best price.

Response: We recognize that there is some cross-over between the data required for the Medicaid drug rebate program, the 340B program, and section 603 of VHCA. However, our regulation is designed to address Medicaid drug rebate best price and average manufacturer price calculations. Due to concerns raised regarding record destruction and the fraud and abuse violations, we also acknowledge the need to increase the record retention period and have chosen a longer 10-year recordkeeping requirement. We expect this longer retention period will alleviate concerns regarding inadvertent record destruction that might impact the 340B program or section 603 of VHCA. We also note that the FCA exists outside the scope of these regulations and applies equally to all of the data provided to the Federal agencies listed and that manufacturers may keep records to support their calculations for all three programs accordingly. With regard to the term, ''authorized government agency,'' our intent was to include any agency with oversight authority and jurisdiction over the Medicaid drug rebate program (for example, the Office of the Inspector General or the Department of Justice).

Comment: One commenter asked for clarification regarding how a manufacturer can provide data supporting its position for periods more than 12 quarters if those data are not to be retained.

Response: In this rule, we are extending the minimum record retention requirement from 3 to 10 years. Therefore, we are requiring that a manufacturer retain data in excess of 12 quarters. Thus, a manufacturer can provide data as may be necessary to substantiate its calculations. Nevertheless, the time limitation for pricing recalculations issued in the August 29, 2003 rule will go into effect on January 1, 2004.

Comment: One commenter expressed concern for manufacturers who find the inconsistent recordkeeping requirements among the Federal drug programs to be confusing. Specifically, if manufacturers are bound by timeframes longer than 3 years, the 3-year recordkeeping requirement in the August 29, 2003 rule is moot. Since we used the 3-year recordkeeping requirement as a reason to justify the 3-year time limitation for price recalculations, we need to reconcile these differences before moving ahead with time limits for pricing changes.

Response: As noted earlier, we acknowledge that different Federal programs may have varying standards in place with regard to recordkeeping; however, we are only regulating the recordkeeping requirements for Medicaid drug rebate pricing data in this rule. We received numerous comments suggesting the 3-year recordkeeping requirements were too short, but none to convince us to expand the time limit on pricing recalculations. We believe that the concerns raised regarding the impact of the recordkeeping requirements on the FCA and State fraud and abuse provisions are compelling. Moreover, because manufacturers are in full possession of the documents that they need to make pricing recalculations, we continue to believe that 3 years is an adequate timeframe to permit manufacturers to recalculate their pricing data. Nevertheless, we want to offer interested parties an opportunity to provide comments about whether a 10-year recordkeeping requirement is the proper timeframe to address the concerns raised on this provision. For these reasons, we are establishing a temporary recordkeeping standard that is longer than the time limitation for price recalculations promulgated in the August 29, 2003 rule and soliciting public comments on the longer standard.

Comment: Two commenters urged us to address comments received on the August 29, 2003 rule and issue a final rule in the near future. One commenter asked when we will publish a final rule.

Response: We are addressing comments that pertain to the provisions in the August 29, 2003 rule in this interim final rule with comment period, which includes a sunset date provision. We anticipate that we will issue a final rule once we have addressed all the comments which we receive on this interim rule.

Comment: Several commenters noted strong opposition to the 3-year recordkeeping requirement, expressing concern with any provision that could permit the destruction of potential evidence of fraud and thereby interfere with efforts to eliminate fraud related to the Medicaid program. One commenter emphasized the importance of the FCA in allowing persons with evidence of fraud against Federal programs or contracts to bring suit on behalf of the government. Another commenter noted that requiring drug manufacturers to maintain their pricing data for only 3 years is a regrettable policy choice that will impose negative financial burdens on providers who participate in the drug pricing program under Section 340B (42 U.S.C. section 256b) of the Public Health Service Act. The commenters noted that there are dozens of pending cases and investigations involving allegations of fraudulent pricing practices by prescription drug manufacturers, many of which look back well beyond the last 3 years. In addition, commenters noted that there are ongoing confidential investigations of similar allegations of fraud that are, by necessity, conducted without notification to the manufacturers. Further, qui tam actions have been filed under seal throughout the country and the preliminary investigation of those matters typically takes place without notice to the manufacturers. The commenters noted that premature destruction of documents concerning average manufacturer prices and best prices could severely hamper these investigations.

Some commenters indicated that a record retention requirement of 6 years, with carve-outs relating to records and data concerning matters under investigation, would strike a more effective balance between efficiency and law enforcement concerns. One commenter recommended a 7-year record retention requirement. Another commenter recommended that we promulgate a recordkeeping requirement with the same substantive standard as that in the FCA: 10 years. That commenter further noted that anything less than a 10-year recordkeeping requirement will seriously undermine the FCA's ability to combat fraud against the Medicaid drug rebate program. Several commenters recommended that we simply remove the recordkeeping requirement.

Response: We concur with commenters who indicated that the 3-year recordkeeping requirement should be increased to address law enforcement concerns. After further consideration, we believe that, due to potential fraud and abuse violations and litigation, a 10-year recordkeeping requirement will be more appropriate and sufficient to ensure a Federal standard with regard to the Medicaid drug rebate program that will not hinder the activities of Federal and State law enforcement officials. Nonetheless, we are soliciting public comment on whether a 10-year recordkeeping requirement is the proper timeframe to address the concerns raised on this provision.

Comment: One commenter questioned the true benefit to manufacturers from the record retention provision in the rule if adjustments can be made to periods older than 3 years under a government investigation.

Response: We recognize the commenter's concerns and note that this provision will have no effect on a manufacturer that correctly calculates its average manufacturer price and best

price. However, we held open the exception to the 3-year period to give all government agencies with oversight authority the opportunity to review manufacturer records and to prevent a manufacturer from claiming that the original 3-year recordkeeping timeframe in any way protected that manufacturer from needing to report correct data. With the new 10-year recordkeeping requirement and its consistency with the FCA, we believe we have made the relationship even clearer.

Comment: In light of ongoing government investigations, one commenter asked whether we still advise manufacturers to discard records that are older than 3 years.

Response: At no time have we advised manufacturers to discard Medicaid drug rebate records. This rule addresses the retention of manufacturer pricing records under the Medicaid drug rebate program and is not designed to provide advice regarding document destruction. We now recognize that the 3-year record retention requirement set forth in the August 29, 2003 rule should be extended in order to address concerns and potential conflicts with Federal and State law enforcement efforts.

We believe that the 10-year recordkeeping requirement is necessary in light of the unique nature of the Medicaid drug rebate program. In particular, we are concerned that because of the way the drug rebate program operates, and the complexity of drug pricing, the program is potentially more susceptible to continuing errors, fraud or abuse. For example, while other programs or activities may be subject to individual, one-time errors, fraud or abuse, the drug rebate program could be more susceptible to such activities via ongoing utilization of a practice, procedure or formula instituted in the past, that is perpetuated and remains undetected. In accordance with section 1927 of the Act and the drug rebate agreement, manufacturers that participate in the drug rebate program submit best price and average manufacturer price with respect to their drugs on a quarterly basis. Manufacturers, not the Secretary, are in possession of the documentation used to substantiate those prices. We believe that the 10-year recordkeeping requirement is necessary in order to preserve critical pricing records and that a timeframe less than 10 years could interfere with efforts to eliminate the documented fraud and abuse related to the drug rebate program.

IV. Provisions of the Interim Final Regulations With Comment Period

This interim final rule with comment period removes the 3-year recordkeeping requirement issued in the August 29, 2003 rule and replaces it with a 10-year recordkeeping requirement from January 1, 2004 through December 31, 2004. This provision will be set forth in 42 CFR part 447 in a new subpart I entitled ''Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements'' at § 447.534(h). Under the 10-year recordkeeping requirement, a drug manufacturer must retain records for 10 years from the date the manufacturer reports that rebate period's data to us. In addition, a manufacturer must retain data beyond the 10-year period if the records are the subject of an audit or a government investigation and if the audit findings or investigation related to the average manufacturer price and best price have not been resolved.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We have, however, submitted a request for emergency approval of the information collection requirements in this final rule. We are requesting an emergency approval because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320, to ensure compliance with the False Claims Act (FCA). We could not reasonably comply with normal clearance procedures because public harm is likely to result if the agency cannot enforce the requirements of the FCA because records may be destroyed.

As stated earlier in this preamble, we are concerned that, without this final rule and implementation of the longer record retention requirement, manufacturers participating in the Medicaid drug rebate program will destroy records concerning drug price calculations, as well as data supporting those calculations after 3 years. If the requirements cannot be implemented immediately, there is a chance that manufacturers could minimize their potential civil liability under the FCA by destroying their Medicaid rebate records through December 31, 2000. As a result, the effective use of the FCA to investigate fraud regarding the Medicaid drug rebate program could be severely limited at a considerable cost to the Federal and State treasuries.

We are requesting OMB review and approval of this collection, with a 180-day approval period. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Therefore, we are soliciting public comment on each of these issues for the following section of this document that contains information collection requirements:

Section 447.534 of this document contains the following information collection requirements.

Under paragraph (h) of § 447.534, there are two recordkeeping requirements:

(1)(i) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports that rebate period's data. The records must include these data and any other materials from which the calculations of the average manufacturer price and best price are derived, including a record of any assumptions made in the calculations. The 10-year timeframe applies to a manufacturer's quarterly submission of pricing data as well as any revised pricing data subsequently submitted to us.

(ii) A manufacturer must retain records beyond the 10-year period if both of the following circumstances exist: (A) The records are the subject of an audit or of a government investigation related to pricing data that are used in average manufacturer price or best price of which the manufacturer is aware, and (B) The audit findings related to the average manufacturer price and best price have not been resolved.

These information collection requirements, except for the timeframe, already exist. The recordkeeping requirements are in the contract

between the drug manufacturer and CMS, with the retention period not specified. The regulation merely revises timeframes specified for maintaining records in the current regulation.

The burden associated with the recordkeeping is minimal. While we have no data on the staffing costs associated with retaining the data, we estimate that it will cost each manufacturer no more than $1.00, the maximum cost of a compact disc for electronic storage per manufacturer, or a total cost maximum cost of $500 per year. (We base the estimate on the assumption that the manufacturers will store 1 year's data per disc, although it is not necessary to have one disc per year.) The cost to manufacturers that maintain paper copies will be even less as they will just have to keep their paper copy of what they submit to us. Again, the staffing costs cannot be estimated at this time.

We will be collecting data on the cost of staffing.

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to the Office of Management and Budget (OMB) for its review of these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Julie Brown, CMS–2175–IFC, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

Comments submitted to OMB may also be emailed to the following address: email: *baguilar@omb.eop.gov*; or faxed to OMB at (202) 395–6974.

VI. Good Cause To Waive the 30-Day Delay in Effective Date

In accordance with section 553(d) of the Administrative Procedure Act (5 U.S.C. 553(d)), final rules ordinarily are not effective until at least 30 days after their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and its reasons in the rule issued.

In this rule, we are removing the 3-year recordkeeping requirement from the August 29, 2003 rule and replacing it with a 10-year recordkeeping requirement for manufacturers that participate in the Medicaid drug rebate program. Due to concerns regarding the FCA and the potential destruction of drug pricing records, we find good cause to waive the 30-day delay in the effective date of the provision in this rule revising the record retention requirement. As discussed below, failure to waive the delay in effective date would be contrary to the public interest. The FCA establishes civil liability for persons or entities who knowingly submit false or fraudulent claims for Federal funds. Essential to the strength of the FCA are its qui tam whistleblower provisions, which allow persons with evidence of fraud against Federal programs or contracts to bring suit on behalf of the government. Qui tam actions are filed under seal and preliminary investigations often take place without notice to manufacturers. While the August 29, 2003 rule would only require manufacturers to keep drug pricing records 3 years following the date the manufacturer first reported the data to us for purposes of average manufacturer price and best price, it could be misinterpreted to permit these records to be discarded for other purposes. As noted, the August 29, 2003 rule would require manufacturers to retain earlier records if they were aware of an unresolved audit or government investigation concerning the manufacturers' average manufacturer price or best price. However, since the manufacturer is often unaware of qui tam investigations, we are concerned that, without this final rule, manufacturers participating in the Medicaid drug rebate program would erroneously conclude that they could discard records concerning drug price calculations, as well as data supporting those calculations that are subject to the FCA and other fraud laws. If the rule is not revised, there is a chance that manufacturers would seek to minimize their potential civil liability under the FCA by discarding their Medicaid rebate records through December 31, 2000. As a result, the effective use of the FCA to investigate fraud regarding the Medicaid drug rebate program could be severely limited at a considerable cost to the Federal and State treasuries. Accordingly, we believe there is a compelling public interest to waive the 30-day delay in effective date for this revision.

VII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely assigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We believe this rule will not have an economically significant effect. We believe the rule will result in neither costs nor savings to the Medicaid program and that additional costs to drug manufacturers will be minimal. We do not consider this rule to be a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million or less in any 1 year. For purposes of the RFA, pharmaceutical manufacturers with 750 or fewer employees are considered small businesses according to the Small Business Administration's size standards matched to the North American Industry Classification System, effective October 1, 2002, *http://www.sba.gov/size/sizetable2002.html*). Use of the Small Business Administration's size standards matched to North American Industry Classification System is in compliance with the Small Business Administration's regulation that set forth size standards for health care industries at 65 FR 69432. Individuals and States are not included in the definition of a small entity. Because pharmaceutical manufacturers are not required to report their number of employees to the Small Business Administration, we are unable to determine how many of them are

considered small entities. This rule will not have a significant impact on small businesses because although some pharmaceutical manufacturers may be small businesses, we estimated that the cost to manufacturers will be minimal, as described in section VII.B below.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not have a significant impact on small rural hospitals because the provisions contained in this final rule do not pertain to hospitals. Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We anticipate this rule will not impact State governments or the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not anticipate this rule will impose direct requirement costs on State governments.

B. Anticipated Effects

1. Effects on Drug Manufacturers

We do not collect information on the costs associated with manufacturer recordkeeping under the Medicaid drug rebate program. Therefore, in the absence of such information, we derived an estimate based on our annual costs of storing electronic pricing data that we receive from approximately 500 drug manufacturers. We store drug product data, including pricing information, for approximately 55,000 drug products. Over the course of the 12 years the Medicaid drug rebate program has been in existence, we have gathered nearly 250 megabytes of information. This information fits on one compact disc. The cost of one blank compact disc is less than $1. We did not have a reasonable proxy available to estimate the staffing costs associated with maintaining the data, so our estimate does not include these costs.

On the whole, we believe this approach is reasonable because it is our understanding that these records are maintained by most manufacturers in an electronic format, while smaller companies may maintain their pricing records in written format. In order to more accurately evaluate the fiscal impact of this provision, we are requesting that manufacturers provide us with information on the costs they would expect to incur pursuant to retaining records for a 10-year period. To the extent possible, we ask that manufacturers make an effort to distinguish between the cost of meeting the 10-year recordkeeping requirement versus other recordkeeping requirements that may apply to the same records.

We do not anticipate that this rule will adversely affect a drug manufacturer's participation in the Medicaid Drug Rebate program or impact the current level of access and availability of prescription drugs for Medicaid beneficiaries. There is no impact on contractors or providers.

2. Effects on the Medicaid Program

We are unable to quantitatively address the burden to States with respect to recordkeeping. This rule will not adversely affect a State's ability to obtain manufacturers' rebates or impact the current level of access and availability of prescription drugs for Medicaid beneficiaries. There is no impact on Medicaid providers or contractors.

C. Alternatives Considered

Retain the 3-year recordkeeping provision in the August 29, 2003 final rule with comment period.

We considered retaining the 3-year recordkeeping provision in the August 29, 2003 final rule with comment period. However, we believe it is necessary to replace the 3-year provision with a 10-year provision to address concerns raised by commenters regarding Federal and State investigations under the FCA and related anti-fraud provisions.

Establish a different time limitation.

Another alternative would be to establish a longer or a shorter recordkeeping requirement. We did not choose a longer recordkeeping timeframe because we believe a 10-year period will offer immediate protection to address situations where investigations are under seal in qui tam actions. Further, the exception to the 10-year requirement adequately addresses situations where investigations known to manufacturers are not yet resolved. We did not choose a shorter recordkeeping timeframe in this rule because we are concerned that such a timeframe could be misconstrued to lead a manufacturer to believe it could prematurely destroy vital evidence in a case of fraud against the government.

Finalize the 10-year requirement without a sunset date provision.

We considered finalizing the 10-year recordkeeping requirement without a sunset date provision. However, we believe that it is important to offer the regulated community an opportunity to provide comments on the impact that such a provision will have before we finalize the 10-year recordkeeping requirement beyond the December 31, 2004 date. In addition, we want to offer interested parties an opportunity to provide comments about whether a 10-year recordkeeping requirement is the proper timeframe to address the concerns raised on this provision.

D. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV part 447 as set forth below:

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart I—Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements

■ 2. In § 447.534, paragraph (h)(1) is revised to read as follows:

§ 447.534 Manufacturer reporting requirements.

* * * * *

(h) *Recordkeeping requirements.* (1)(i) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports that rebate period's data to CMS. The records must include these data and any other materials from which the calculations of the average manufacturer price and best price are derived, including a record of any assumptions made in the calculations. The 10-year timeframe applies to a manufacturer's quarterly submission of pricing data as well as any revised pricing data subsequently submitted to CMS.

(ii) A manufacturer must retain records beyond the 10-year period if both of the following circumstances exist:

(A) The records are the subject of an audit or of a government investigation related to pricing data that are used in average manufacturer price or best price of which the manufacturer is aware.

(B) The audit findings or investigation related to the average manufacturer price and best price have not been resolved.

(2) The provisions in paragraph (h)(1) of this section concerning record retention terminate on December 31, 2004.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: December 29, 2003.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 29, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–32329 Filed 12–31–03; 12:47 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket No. FEMA–D–7549]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the Base (1% annual chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

DATES: These modified BFEs are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Director reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities.

The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This interim rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, floodplains, reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows:

ATTACHMENT B

Enclosure A

REBATE AGREEMENT
Between
The Secretary of Health and Human Services
(hereinafter referred to as "the Secretary")
and
The Manufacturer Identified in Section XI of this Agreement
(hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" means the AMP for the 7/l/90-9/30/90 quarter for purposes of computing the AMP as of 10/l/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f)"Centers for Medicare & Medicaid Services (CMS)" (formerly HCFA) means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(h) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

(k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC

number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.

(t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u) “Quarter” means calendar quarter unless otherwise specified.

(v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w) “Secretary” means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(y) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(z) "Single Source Drug" will have the meaning set forth in Section 1927 (k) (7) (A) (iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa) "States" means the 50 states and the District of Columbia.

(bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

III SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

IV PENALTY PROVISIONS

(a) The Secretary may impose a civil monetary penalty under III(b), up to $100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

VI DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

VII CONFIDENTIALITY PROVISIONS

(a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

VIII NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

IX GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

Center for Medicaid and State Operations
Family and Children's Health Programs Group
Division of Benefits, Coverage and Payment
Post Office Box 26686
Baltimore, MD 21207-0486

Notices to CMS concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations
Finance, Systems and Quality Group
Division of State Systems
Post Office Box 26686
Baltimore, MD 21207-0486

The CMS address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to CMS at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By:_____ _____
Date

Title: Deputy Director
Finance, Systems and Quality Group
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____ _____
(signature) (please print name)

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code(s): _____

Date: _____